

10/527246

REC'D 11 JUL 2005	
WIPO	PCT

## PATENT COOPERATION TREATY

## PCT

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference AHP98246	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/US03/28519	International filing date (day/month/year) 11 September 2003 (11.09.2003)	Priority date (day/month/year) 16 September 2002 (16.09.2002)
International Patent Classification (IPC) or national classification and IPC IPC(7): A61K 39/15, 39/235, 39/295 and US Cl.: 424/202.1, 215.1, 233.1		
Applicant WYETH		
<p>1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>7</u> sheets, including this cover sheet.</p> <p><input type="checkbox"/> This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).</p> <p>These annexes consist of a total of <u>   </u> sheets.</p> <p>3. This report contains indications relating to the following items:</p> <p>I <input checked="" type="checkbox"/> Basis of the report</p> <p>II <input type="checkbox"/> Priority</p> <p>III <input type="checkbox"/> Non-establishment of report with regard to novelty, inventive step and industrial applicability</p> <p>IV <input type="checkbox"/> Lack of unity of invention</p> <p>V <input checked="" type="checkbox"/> Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability, citations and explanations supporting such statement</p> <p>VI <input type="checkbox"/> Certain documents cited</p> <p>VII <input type="checkbox"/> Certain defects in the international application</p> <p>VIII <input type="checkbox"/> Certain observations on the international application</p>		
Date of submission of the demand 29 March 2004 (29.03.2004)	Date of completion of this report 28 June 2005 (28.06.2005)	
Name and mailing address of the IPEA/US Mail Stop PCT, Attn: IPEA/ US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703) 305-3230	Authorized officer Shanon Foley <i>Shanon Foley</i> Telephone No. (703) 308-0196	

Form PCT/IPEA/409 (cover sheet)(July 1998)

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US03/28519

## I. Basis of the report

## 1. With regard to the elements of the international application:\*

- ☒ the international application as originally filed.
- ☒ the description:  
pages 1-40 as originally filed  
pages NONE, filed with the demand  
pages NONE, filed with the letter of \_\_\_\_\_.
- ☒ the claims:  
pages 41 and 42 as originally filed  
pages NONE, as amended (together with any statement) under Article 19  
pages NONE, filed with the demand  
pages NONE, filed with the letter of \_\_\_\_\_.
- ☒ the drawings:  
pages NONE as originally filed  
pages NONE, filed with the demand  
pages NONE, filed with the letter of \_\_\_\_\_.
- ☐ the sequence listing part of the description:  
pages NONE as originally filed  
pages NONE, filed with the demand  
pages NONE, filed with the letter of \_\_\_\_\_.

## 2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language \_\_\_\_\_ which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

## 3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in printed form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☒ The amendments have resulted in the cancellation of:

- ☒ the description, pages NONE
- ☒ the claims, Nos. NONE
- ☒ the drawings, sheets/fig NONE

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).\*\*

\* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

\*\* Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.  
PCT/US03/28519**V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement****1. STATEMENT**

Novelty (N)	Claims <u>NONE</u>	YES
	Claims <u>1-10</u>	NO
Inventive Step (IS)	Claims <u>NONE</u>	YES
	Claims <u>1-10</u>	NO
Industrial Applicability (IA)	Claims <u>1-10</u>	YES
	Claims <u>NONE</u>	NO

**2. CITATIONS AND EXPLANATIONS**

Claims 1-3 and 5-10 lack novelty under PCT Article 33(2) as being anticipated by Sharma (US 6,406,702 B1), or, in the alternative, van Loon (EP 1 024 189 A1).

Claims 1-10 are drawn to a vaccine comprising an avian reovirus and an avian adenovirus against conditions associated with Avian Malabsorption Syndrome. The claims also encompass the addition of a Birna-like virus (infectious bursal disease virus) as well as a method of vaccinating with the vaccine and a method of making the vaccine by combining the components.

Sharma et al. anticipate a vaccine comprising an avian reovirus, an avian adenovirus and infectious bursal disease virus as well as methods of making the vaccine by admixing the components and vaccinating avians with the vaccine, see column 4, lines 29-35, column 8, lines 15-24 and claims 1-27. Sharma also anticipate equivalent doses recited in the instant claims since the vaccine induces therapeutic and protective efficacy.

Although Sharma does not discuss Avian Malabsorption Syndrome, the vaccine and the methods taught by the reference inherently comprise the essential ingredients required to vaccinate against Avian Malabsorption Syndrome. Therefore, the teachings of Sharma anticipate the instant claims.

Claim 4 lacks an inventive step under PCT Article 33(3) as being obvious over Sharma in view of van Loon.

The claim requires that the vaccine be inactivated. Sharma does not teach this limitation. However, van Loon teaches that inactivated vaccines induce protective antibodies for extended periods, see page 5, lines 52-54. Therefore, one of ordinary skill in the art at the time the invention was made would have been motivated to incorporate inactivated vaccines into the composition of Sharma to extend the production of protective antibodies. One of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of success for including inactivated forms of van Loon in the vaccine of Sharma because Sharma teaches that any commercially known vaccine may be combined with vaccine, see column 4, lines 60-63. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, absent unexpected results to the contrary.

Claims 1-10 lack novelty under PCT Article 33(2) as being anticipated by van Loon (EP 1 024 189 A1).

Van Loon anticipate a vaccine comprising a live or inactivated avian reovirus, an avian adenovirus and infectious bursal disease virus as well as methods of making the vaccine by admixing the components and vaccinating avians with the vaccine with the required effective dose against malabsorption syndrome. See page 2, lines 1-19, page 3, lines 35-36 and line 58 to page 4, line 1, page 5, line 4 to page 7, line 34 and claims 1-12.